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EXAMINER

GOLDBERG, J

| ART UNIT | PAPER NUMBER |
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Date mailed 01/03/01

Paper No. 17

Application Number: 09/137,822
Filing Date: August 21, 1998
Appellant(s): NAESBY, MICHAEL

Hans J. Crosby
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed November 8, 2000.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: Appellant indicated Claims 31-85 were rejected under 35

U.S.C. 102(b) as being unpatentable over Svinarchuk et al. (j. Biol. Chem. 1995, Vol. 270(23), pages 14068-71).

However, the final rejection of March 10, 2000 indicated that only Claims 31, 32, 34-36, 42-43, 55-56, 58, 63-64, 69-70 and 72 have been rejected as being anticipated by Svinarchuk.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 31-85 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Svinarchuk et al. "An unusually stable Purine(Purine-Pyrimidine) Short Triplex" J. Biol. Chem. Vol. 270, No. 23, (June 1995), pp. 14068-71.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claim 31-85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amended claims, reference to "the aggregate", "aggregate binding regions" are included. The amendment proposes that the new claim language clarifies the issue. However, the specification does not describe or discuss "aggregates". Instead the specification describes a triple stranded binding region with two independent probes C1 and C2 (pg. 18). This description does not support aggregate. The definition of aggregate recognized in Stedman's dictionary as "aggregate" is "to unite or come together in a mass or cluster". However, this definition sheds little light on the intended meaning of both "the aggregate" and "aggregate binding regions" as it pertains to the claimed invention. The concept of "forming aggregates" does not appear to be part of the originally filed invention. Therefore, "aggregate" constitutes new matter.

Response to Arguments

Appellants traverse the rejection. The brief asserts that the term "the aggregate" and "aggregate binding regions" are not new matter. The brief states that " although the word aggregate does not appear in the application as filed, there is no requirement that words used in claims must exactly match those used in the specification. The examiner has acknowledged that this is true. However, the specification does not "reasonably convey to persons skilled in the art that, as of the filing date, the inventors had possession of the subject matter later claimed". The specification instead describes a triple stranded binding region with two independent probes C1 and C2 (pg. 18). This description does not support aggregate. The examiner does not disagree with the

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assertion that two or more probes C may be used, the examiner believes that the use of aggregate carries meanings which have not been supported in the specification. For example, the definition of aggregate recognized in Stedman's Medical dictionary of "aggregate" is "to unite or come together in a mass or cluster". Furthermore, in a distinct medical dictionary, Merriam-Webster's Medical Desk Dictionary, aggregate means "a group of species, other than a subgenus, within a genus, or a group of subspecies within a species. An aggregate may be denoted by a group name interpolated in parentheses." The specification does not provide any support for a "mass or cluster" binding region. The independent probes of C1 and C2 bind in a specific manner rather than in a "mass or cluster". Claims 31-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claims 31-85 are indefinite over the recitation "in the aggregate" because "in the aggregate" lacks antecedent basis.

Response to Arguments

The claims were rejected as indefinite over the recitation "in the aggregate" because "in the aggregate lacks antecedent basis". The brief does not appear to address this rejection.

3. Claims 31-85 are indefinite over the recitation "an aggregate binding region" because it is unclear what "an aggregate binding region" includes. It

is unclear whether the aggregate binding region is located on A or C. Further, it is unclear what physical and chemical feature define the aggregate binding region.

Response to Arguments

The brief traverses the rejection. The brief asserts that "an aggregate binding region" is clear and definite because those skilled in the art would understand the meaning of the phrases "aggregate" and "aggregate binding region" as used in the context of the claims as considered in light of the teachings of the application as filed. Moreover, the brief argues that the examiner is incorrect in the statement that since "aggregate" has more than one possible definition, the term is unclear. This argument has been reviewed but is not convincing because as previously stated, it is unclear whether the aggregate binding region is located on nucleic acid A or located on nucleic acid probe C and what physical and chemical features define the aggregate binding region. Additionally, with respect to the two distinct definitions, the skilled artisan would not clearly understand the intended meaning of aggregate in the claimed invention. The examiner provided the two different definitions as an indication that the term had more than one meaning and to show that the use of the term "aggregate" in the instant claims made the invention unclear. Since the specification does not clearly provide a definition for aggregate, the skilled artisan would be unclear of the definition. Furthermore, the examiner has offered evidence why the term was indefinite, namely it is unclear whether the aggregate binding region is located on nucleic acid A or located on nucleic acid probe C and what physical and chemical features define the aggregate binding region.

4. Claims 31, 32, 34-36, 42-43, 55, 56, 58, 63-64, 69, 70, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Svinarchuk (J Biol Chem 1995 Jun 9;270(23):14068-71).

Svinarchuk teaches triple helix formation in which "the stability of double-stranded DNA is increased by the binding of the third strand"(abstract).

Oligonucleotides were synthesized and labeled (Pg 14068, Col 2, Para 2). The triple helix was formed and monitored by 5% polyacrylamide gel electrophoresis (Pg 14068, Col 2, Para 2). The thermostability was monitored by a thermometer (Pg 14068, Col 2, Para 2). As seen in Figure 3, there is only one nucleic acid binding probe C in the triple stranded region, nucleic acid binding probe B is smaller than nucleic acid binding probe C, nucleic acid binding probe C has a length of at least 6, nucleic acid binding probe B is capable of having either an asymmetrical or a symmetrical base sequence, nucleic acid binding probe B is bound to nucleic acid A via Hoogsteen base pairing while nucleic acid binding probe C is bound to nucleic acid A via Watson and Crick binding, and nucleic acid binding probe C fully spans the region of nucleic acid binding probe B.

It is noted that Svinarchuk teaches a double stranded molecule with a probe hybridized to a specific region. However, as written, the independent claims do not include specific size requirements for nucleic acid binding probe C. Therefore teachings of a double stranded molecule encompass the limitations of the claims. Furthermore, Svinarchuk teaches radiolabeling oligonucleotides and detecting (monitoring) by gel electrophoresis. Thus, Svinarchuk teaches detection of the triplex formation.

Response to Arguments

It is noted that ONLY claims 31, 32, 34-36, 42-43, 55-56, 58, 63-64, 69-70 and 72 have been rejected over Svinarchuk et al. (herein referred to as Svinarchuk).

The brief traverses the rejection. Svinarchuk teaches a double stranded molecule with a probe hybridized to a specific region and that Svinarchuk teaches detection of the triplex formation. The brief asserts that this teaching does not teach two binding probes. The brief asserts that the examiner did not provided any specific arguments with respect to this rejection. The examiner did provide basis for maintaining the rejection as exemplified by "The breif asserts that Svinarchuk does not involve two binding probes B and C, however, as previously stated the claims do not include specific size requirements from nucleic acid binding probe C and thus a double stranded molecule is encompassed by the claims. Thus, claims which are drawn to a single nucleic acid binding probe C are anticipated by Svinarchuk.(last sentences of the Adivsory Action, July 20, 2000)". Moreover, the examiner acknowledged this potential point of interest when the initial rejection was made. Specifically the examiner stated, "It is noted that Svinarchuk teaches a double stranded molecule with a probe hybridized to a specific region. However, as written, the independent claims do not include specific size requirements for nucleic acid binding probe C. Therefore teachings of a double stranded molecule encompass the limitations of the claims. Furthermore, Svinarchuk teaches radiolabeling oligonucleotides and detecting (monitoring) by gel electrophoresis. Thus, Svinarchuk teaches detection of the triplex formation."

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With regard to point "a" directed to Claims 31-36, 41-47, 55-58, 62-64, 69-72 and 76-77, several of these claims were not rejected in this rejection. With respect to 31, 32, 34-36, 42-43, 55-56, 58, 63-64, 69-70 and 72, the recitation "probe" is an intended use and does not confer any structural limitations. The term probe does not contain any size limitation or structural characteristics which distinguish it from the nucleic acid provided in Svinarchuk. The art teaches that whole chromosomes may be used as probes, thus, it is a reasonable interpretation that a 37-base pair strand of DNA may be considered a probe. The specification does not appear to explicitly define probe. The definition provided in the brief, "a substance (as DNA in genetic research) used to obtain specific information for diagnostic or experimental purposes" further supports the examiner's position that "probe" does not confer any size limitation or structural characteristics. The statement provided, "not every nucleic acid molecule can be properly characterized as a probe and importantly a probe is something that is used to interrogate or explore in order to obtain information about the object of the investigation" is not supported by the definition provided in the specification. The specification does not provide any basis for the broad statement. A probe is simply a piece of nucleic acid and the art teaches nucleic acids may be used as a probe. Furthermore, this definition does not differentiate the probe of the invention from the nucleic acid of Svinarchuk because it contains no structural information. Thus probe in the sense that it is used to "interrogate or explore in order to obtain information about the object of the investigation" is an intended use which does not carry weight.

With regard to point "b" directed to Claims 37-40, 59-61, 73-75, 82-85, the discussion is moot since ONLY Claims 31, 32, 34-36, 42-43, 55-56, 58, 63-64, 69-70 and 72 were rejected over Svinarchuk.

With regard to point "c" directed to Claims 48-52, 65-66, 78-79, the discussion is moot since ONLY Claims 31, 32, 34-36, 42-43, 55-56, 58, 63-64, 69-70 and 72 were rejected over Svinarchuk.

With regard to point "d" directed to Claims 53-54, 67-68, and 80-81, the discussion is moot since ONLY Claims 31, 32, 34-36, 42-43, 55-56, 58, 63-64, 69-70 and 72 were rejected over Svinarchuk.

For the above reasons, it is believed that the rejections should be sustained.

(11) Response to Argument

The arguments have been fully responded to under the grounds of rejection above.

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Respectfully submitted,

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December 28, 2000

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